

**REMARKS****A. Status of Claims**

Claims 97-99, 116-122, 133-137, 141-143 and 150 are currently pending. Claim 97 has been amended to address the examiner's newly raised concerns with respect to dependent claims 98 and 116, to clarify that the aqueous secondary solvent will optionally comprise a lipid component such as is the case in the context of Applicant's preferred secondary solvent, an aqueous lipid emulsion.

Applicants submit that the amendments to the present claims are appropriate in light of the fact that a new rejection of claims 98 and 116 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph was entered in the Final Office Action. This rejection is discussed in more detail below.

Claims 94-96, 106-115, 123-132, 138-140 and 144-149 currently stand withdrawn on the basis of the Action's position that there was previously no allowable generic claim. For reasons set forth below, it is submitted that a generic linking claim, claim 97, is now allowable and, thus, reinstatement of these withdrawn claims is respectfully requested. Upon reinstatement, these claims will require some amendment to change dependencies from claim 93 to 97 (claims 94-96, 106-107, 109, 129-133, 138-139). Further, upon reinstatement Applicant will desire to amend claims 107 and 109 to clarify that "more than" 95% and 97%, respectively, of the solvent or acid is removed.

**B. Section 112, Second Paragraph Rejections**

The Action first rejects claims 98 and 116, raising, for the first time in this prosecution, the issue of how both a lipid solution and water could both be considered an "aqueous solvent" as required by claim 97.

In response to this rejection, base claim 97 has been amended to clarify that the aqueous solvent preferably includes a lipid component, such as a lipid emulsion. See specification, for example, at bottom of page 4. There is certainly nothing inconsistent or indefinite about an aqueous solvent that includes a lipid component. It is believed that this amendment should adequately address the Examiner's concerns, but if not, he is requested to contact the undersigned or suggest language that would address those concerns.

### C. Prior Art Issues

The previous Action did not reject claim 97 over the prior art, and claim 97 was placed into independent form in order to place it into condition for allowance. Thus, Applicants were surprised that the Examiner not only failed to allow the claims but made the Action final. Nevertheless, Applicant will respond as it is believed that the Examiner has perhaps failed to appreciate the distinctions between the art relied on and the subject matter of the claims. The Action apparently takes the position that Szoka is relevant to patentability in that it is said to teach removal of the aprotic solvent by dialysis and concentration, and that the newly cited secondary references of Smith or Corbiere teaches resuspension in an aqueous composition.

In response, we first note that the Szoka patents appear, as pointed out by the Examiner, to teach removal of the dipolar aprotic solvent by dialysis. See, e.g., col. 12, lines 34-54 of the '914 patent. However, while dialysis would be expected to remove the dipolar aprotic solvent, dialysis would not remove more than 50% of the "aqueous secondary solvent" as specified in step (c) of claim 97. The Examiner appears to recognize this shortcoming in the rejection, in that the Action further states that Szoka teaches that the formulations can be "concentrated," referring to col. 3, lns 15-16. However, it should be noted that the claim requires "reconstitution" with an pharmacologically acceptable aqueous solvent *following* the removal of more than 50% of the

secondary solvent. However, Szoka teaches away from the addition of further aqueous solution following "concentration": First, there does not appear to be any teaching or suggestion to add additional aqueous solvent after concentration and, secondly, a principal goal of Szoka is to achieve "high concentrations of liposomes" (see, e.g., col. 2, line 68). Thus, when the passage re "concentrated" at col. 3, lns 15, is read in light of the passage in the previous paragraph re "high concentration of liposomes" it is evident that one of skill would not seek to add back additional aqueous solvent following concentration as that would defeat the purpose of the invention.

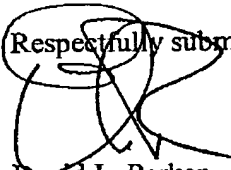
The newly cited secondary references are not combinable with Szoka for the reasons stated above – that the further addition of a second round of aqueous solvent after concentration would defeat the purpose of the Szoka teaching re "high concentrations of liposomes."

For the foregoing reasons, the Examiner is requested to reconsider and withdraw the rejection, and permit applicant the right to reintroduce the withdrawn claims.

**E. Conclusion**

Applicants respectfully request favorable consideration of this case in view of the above. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicant's representative at (512)-536-3055.

Respectfully submitted,

  
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